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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,936	07/03/2001	Paul DiCarlo	BSI-479US	1985

7590

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EXAMINER

LANDREM, KAMRIN R

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/898,936

Applicant(s)

DICARLO, PAUL

Examiner

Kamrin R. Landrem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15, 25-27 and 35-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 25-27 and 35-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 15 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (USPN 5,522,881) in view of Sparer et al (USPN 6,159,240).

With regards to amended Claim 1, Lentz discloses in Figure 4 a prosthetic component 10 having proximal 14 and distal 16 ends comprising a graft extending between ends having a hem 20,22 formed on said ends. Lentz discloses the claimed device for implantation into a body lumen however Lentz fails to disclose the particulars of the cord disposed within the hem. Sparer teaches the use of an expandable cord 32 disposed within interior space for absorbing fluid for aiding fixation of prosthetic component 30 against body lumen (Figure 4 and 6:14-45). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the prosthetic component 10 of Lentz by incorporating the expandable cord 32 disclosed by Sparer in order to securely position the component 10 within the body lumen.

With regards to amended Claim 25, Lentz as modified by Sparer also discloses the method of implanting a device in a body lumen comprising the steps of introducing a prosthetic component 10 comprising a graft having a hems 20,22 defining an interior space and a cord 32 disposed within interior space for absorbing fluid for aiding fixation of prosthetic component 10

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against body lumen, and contacting said cord 32 with fluid to aid fixation against body lumen (3:33-8:30 of Lentz).

New claims 35,39, and 40 are is rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (USPN 5,522,881) in view of Sparer et al (USPN 6,159,240). See above discussion.

New claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (USPN 5,522,881) in view of Sparer et al (USPN 6,159,240). See above discussion.

New claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (USPN 5,522,881) in view of Sparer et al (USPN 6,159,240). See above discussion for particulars of prosthetic device. Lentz as modified by Sparer discloses the claimed device for implantation into the body lumen however Lentz fails to disclose the thickness of the cord 32 prior to implantation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the cord small (i.e. less than thirty thousandths of an inch), since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art (see MPEP 2144.04).

New claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (USPN 5,522,881) in view of Sparer et al (USPN 6,159,240). See above discussion for particulars of the prosthetic device. Lentz discloses (2:16-29) that the prosthetic component 10 is radially self- expanding to conform to a shaped and inner surface of a lumen into which it is implanted (2:16-29).

New claim 41 is 35 U.S.C. 103(a) as being unpatentable over Lentz (USPN 5,522,881) as modified by Sparer et al (USPN 6,159,240) further in view of Berg et al (USPN 6,371,982).

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As discussed above, Lentz as modified by Sparer discloses the device for implantation in a body lumen as claimed however Lentz fails to disclose variable porosity along the stents length. Berg teaches a tubular graft with variable porosity/permeability along the length of the graft (see Figures 4a and 7a) to enhance the compliance properties of the graft. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the porosity of the graft as disclosed by Lentz at the ends (the area of the hems) as taught by Berg to enable more fluid to be in contact with expandable cord 32.

New claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (USPN 5,522,881) in view of Sparer et al (USPN 6,159,240).

As discussed above, Lentz as modified by Sparer discloses the device for implantation in a body lumen. Additionally Lentz discloses the method of inserting the component 10 by means of a delivery catheter (4:67) to the predetermined target area wherein the component 10 is expanded by a balloon catheter. Upon expansion the cord 32 would contact fluid and thereby aid to fixate the expanded device 10 into the walls of the body lumen. Upon expansion the delivery catheter (the impediment to flow) is removed thereby allowing fluid to flow through lumen of device 10 and contact hemmed areas containing cord 32.

***Response to Amendment/ Arguments***

Amendments to claims 1 and 25 as well as addition of new claims fail to render the pending claims patentably distinguishable over the prior art. Please see body of action for discussion of claims.

The indicated allowability of claims 2,4,6,11-14,26, and 27 is withdrawn in view of the newly discovered reference(s) Lentz and Berg. Rejections of new claims 34-43 based on the newly cited reference(s) are discussed above.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kamrin Landrem  
Examiner  
AU 3738

KRL



David J. Isabella  
Primary Examiner